

Notice of Public Hearing

Pursuant to Section 22215 of Public Act 306 of 1969, as amended, the Michigan Department of Health and Human Services (MDHHS) will hold a hearing on Certificate of Need (CON) Review Standards.

Pursuant to MCL 15.263(2), MCL 15.263a(1)(b)(ii), City of Lansing City Council Resolution 2021-056, and Ingham County Board of Commissioners Resolution 21-138, this hearing will be held virtually via Zoom.

Date: Tuesday, April 27, 2021

Time: 9:30 a.m.

Topic: Cardiac Catheterization Public Hearing

Join from PC, Mac, Linux, iOS or Android: <https://michigan-host.zoom.us/j/81835352669>

Or by Telephone:

USA (215) 446-3656

USA (888) 363-4734 (US Toll Free)

Conference code: 212089



The proposed language changes include the following:

1. Section 2(1): Added and moved/modified definitions as follows:

(b) "APPLICANT" MEANS ONE OF THE FOLLOWING TYPES OF FACILITIES:

(i) AMBULATORY SURGICAL CENTER (ASC) WHICH IS DEFINED AS ANY DISTINCT ENTITY CERTIFIED BY MEDICARE AS AN ASC UNDER THE PROVISIONS OF TITLE 42, PART 416 THAT OPERATES EXCLUSIVELY FOR THE PURPOSE OF PROVIDING SURGICAL SERVICES TO PATIENTS NOT REQUIRING HOSPITALIZATION.

(ii) FREESTANDING SURGICAL OUTPATIENT FACILITY (FSOF) WHICH IS DEFINED AS A HEALTH FACILITY LICENSED UNDER PART 208 OF THE CODE. IT DOES NOT INCLUDE A SURGICAL OUTPATIENT FACILITY OWNED AND OPERATED AS A PART OF A LICENSED HOSPITAL SITE. A FREESTANDING SURGICAL OUTPATIENT FACILITY IS A HEALTH FACILITY FOR PURPOSES OF PART 222 OF THE CODE.

(iii) Hospital WHICH IS DEFINED AS a health facility licensed under Part 215 of the Code.

[Merged/modified from previous subsection (r)].

(g) "CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED) PROCEDURE" MEANS IMPLANTATION OF TRANSVENOUS SINGLE AND DUAL CHAMBER PACEMAKER, TRANSVENOUS SINGLE AND DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS), AND ALL GENERATOR CHANGES.

(t) "EXCESS PROCEDURE EQUIVALENTS" MEANS THE NUMBER OF PROCEDURE EQUIVALENTS PERFORMED BY AN EXISTING CARDIAC CATHETERIZATION SERVICE IN EXCESS OF 1200 PER CARDIAC CATHETERIZATION LABORATORY AND 300 PCI SESSIONS (810 PROCEDURE EQUIVALENTS) PER SERVICE. THE NUMBER OF CARDIAC CATHETERIZATION LABORATORIES USED TO COMPUTE EXCESS PROCEDURE EQUIVALENTS SHALL INCLUDE BOTH EXISTING AND APPROVED BUT NOT YET OPERATIONAL CARDIAC CATHETERIZATION LABORATORIES. IN THE CASE OF A CARDIAC CATHETERIZATION SERVICE THAT OPERATES OR HAS A VALID CON TO OPERATE MORE THAN ONE LABORATORY AT THE SAME SITE, THE TERM

MEANS NUMBER OF PROCEDURE EQUIVALENTS IN EXCESS OF 1200 MULTIPLIED BY THE NUMBER OF CARDIAC CATHETERIZATION LABORATORIES AT THE SAME SITE. FOR EXAMPLE, IF A CARDIAC CATHETERIZATION SERVICE OPERATES, OR HAS A VALID CON TO OPERATE, 2 CARDIAC CATHETERIZATION LABORATORIES AT THE SAME SITE, THE EXCESS PROCEDURE EQUIVALENTS IS THE NUMBER THAT IS IN EXCESS OF 2400 PROCEDURE EQUIVALENTS AND IN EXCESS OF 300 PCI SESSIONS (810 PROCEDURE EQUIVALENTS).

2. Section 4(2): New requirements to allow for an FSOF to initiate diagnostic cardiac catheterization and elective PCI.

(2) AN APPLICANT FSOF PROPOSING TO INITIATE DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI SHALL DEMONSTRATE THE FOLLOWING:

(a) THE APPLICANT HAS IDENTIFIED AT LEAST ONE INTERVENTIONAL CARDIOLOGIST TO PERFORM THE DIAGNOSTIC CARDIAC CATHETERIZATIONS AND PCI PROCEDURES WHO HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR DURING THE MOST RECENT 24-MONTH PERIOD PRECEDING THE DATE THIS APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE INTERVENTIONAL CARDIOLOGIST SHALL HAVE COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING PROGRAM, BE BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY, HAVE PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY OPERATOR, AND HAVE A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.

(b) THE APPLICANT HAS IDENTIFIED NURSING AND TECHNICAL CATHETERIZATION LABORATORY STAFF THAT ARE EXPERIENCED IN HANDLING ACUTELY ILL PATIENTS AND COMFORTABLE WITH INTERVENTIONAL EQUIPMENT AND HAVE ACQUIRED EXPERIENCE IN DEDICATED INTERVENTIONAL LABORATORIES AT AN OHS HOSPITAL. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

(c) THE APPLICANT HAS IDENTIFIED CARDIAC CARE UNIT NURSES WHO ARE ADEPT IN HEMODYNAMIC MONITORING AND IABP MANAGEMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

(d) THE LABORATORY OR LABORATORIES WILL BE EQUIPPED WITH OPTIMAL IMAGING SYSTEMS, RESUSCITATIVE EQUIPMENT, AND INTRA-AORTIC BALLOON PUMP (IABP) SUPPORT, AND STOCKED WITH A BROAD ARRAY OF INTERVENTIONAL EQUIPMENT. THE LABORATORIES WILL BE EQUIPPED WITH SYSTEMS FOR ASSESSING HEMODYNAMIC SIGNIFICANCE OF CORONARY LESIONS (I.E., FFR, IFR, OR OTHER) AND INTRACORONARY IMAGING TECHNOLOGY (I.E., IVUS OR OCT) FOR ENSURING PCI OPTIMIZATION.

(e) A WRITTEN AGREEMENT WITH AN OHS HOSPITAL THAT IS WITHIN 30 MINUTES TRAVEL TIME THAT INCLUDES ALL OF THE FOLLOWING:

(i) INVOLVEMENT IN CREDENTIALING CRITERIA AND RECOMMENDATIONS FOR PHYSICIANS APPROVED TO PERFORM PCI PROCEDURES.

(ii) PROVISION FOR ONGOING CROSS-TRAINING FOR PROFESSIONAL AND TECHNICAL STAFF INVOLVED IN THE PROVISION OF PCI TO ENSURE FAMILIARITY WITH INTERVENTIONAL EQUIPMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

(iii) REGULARLY HELD JOINT CARDIOLOGY/CATHETERIZATION LABORATORY CONFERENCES TO INCLUDE REVIEW OF PCI CASES.

(iv) DEVELOPMENT AND ONGOING REVIEW OF PATIENT SELECTION CRITERIA FOR PCI PATIENTS AND IMPLEMENTATION OF THOSE CRITERIA.

(v) A MECHANISM TO PROVIDE FOR APPROPRIATE PATIENT TRANSFERS BETWEEN FACILITIES AND AN AGREED PLAN FOR PROMPT CARE.

(vi) WRITTEN PROTOCOLS, SIGNED BY THE APPLICANT AND THE OHS HOSPITAL, FOR THE IMMEDIATE TRANSFER FROM THE CARDIAC CATHETERIZATION LABORATORY TO EVALUATION ON SITE IN THE OHS HOSPITAL, OF PATIENTS REQUIRING SURGICAL EVALUATION AND/OR INTERVENTION 365 DAYS A YEAR. THE PROTOCOLS SHALL BE REVIEWED AND TESTED ON A QUARTERLY BASIS.

(vii) CONSULTATION ON FACILITIES, EQUIPMENT, STAFFING, ANCILLARY SERVICES, AND POLICIES AND PROCEDURES FOR THE PROVISION OF INTERVENTIONAL PROCEDURES.

(f) A WRITTEN PROTOCOL SHALL BE ESTABLISHED AND MAINTAINED FOR CASE SELECTION FOR THE PERFORMANCE OF PCI CONSISTENT WITH THE CASE SELECTION CRITERIA DOCUMENTED IN THE SCAI POSITION STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9).

(g) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN PCI SERVICES WITHOUT ON-SITE OHS SERVICES, AND THE APPLICANT SHALL IDENTIFY A PHYSICIAN POINT OF CONTACT FOR THE DATA REGISTRY.

(h) CATH LAB FACILITY REQUIREMENTS SHALL CONFORM TO THE POSITION STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9). THE APPLICANT SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THE PRINCIPLES DOCUMENTED IN THIS POSITION STATEMENT IN THEIR APPLICATION.

(i) THE APPLICANT SHALL PROJECT THE FOLLOWING BASED ON VERIFIABLE DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT, AS APPLICABLE:

(i) IF THE APPLICANT IS PROPOSING A SINGLE LAB, AT LEAST 750 PROCEDURE EQUIVALENTS TOTAL, INCLUDING AT LEAST 540 PROCEDURES EQUIVALENTS FROM ELECTIVE PCIs (200 PCI SESSIONS).

(ii) IF THE APPLICANT IS PROPOSING MULTIPLE LABS, AT LEAST 1,000 PROCEDURE EQUIVALENTS PER LAB, INCLUDING AT LEAST 540 PROCEDURE EQUIVALENTS TOTAL FROM ELECTIVE PCIs (200 PCI SESSIONS).

(j) THE APPLICANT SHALL HAVE OR OBTAIN WITHIN 12 MONTHS OF BEGINNING OPERATIONS AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS). AN APPLICANT THAT DOES NOT CURRENTLY HOLD THE CERTIFICATION SHALL ATTEST THAT THE CERTIFICATION WILL BE OBTAINED WITHIN 12 MONTHS OF BEGINNING OPERATIONS.

3. Section 4(3): New requirements to allow for an FSOF to perform CIED procedures.

(3) AN APPLICANT FSOF PROPOSING TO PERFORM CIED PROCEDURES SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(a) THE FSOF IS APPROVED TO PERFORM DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI OR IS APPLYING TO PROVIDE BOTH OF THOSE SERVICES AS A PART OF THIS APPLICATION.

(b) THE APPLICANT IS LOCATED LESS THAN 30 MINUTES TRAVEL TIME FROM A HOSPITAL WITH OHS SERVICE.

(c) THE APPLICANT HAS OR WILL HAVE CARDIAC CATHETERIZATION LAB CAPABILITIES INCLUDING PERICARDIOCENTESIS EQUIPMENT ON SITE.

(d) THE APPLICANT HAS IDENTIFIED AT LEAST ONE PHYSICIAN WHO MEETS ALL OF THE FOLLOWING:

(i) IS CARDIOLOGY BOARD CERTIFIED FOR PERMANENT PACEMAKER IMPLANTS;

(ii) IS EP BOARD CERTIFIED FOR ICD IMPLANTS;

(iii) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND ADMITTING AT THE TERTIARY CARE HOSPITAL IDENTIFIED IN (3)(b);

(iv) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER; AND

(v) HAS IMPLANTED AT LEAST 75 DEVICES AS THE PRIMARY OPERATOR IN THE PREVIOUS 2 YEARS POST FELLOWSHIP TRAINING.

(e) THE APPLICANT SHALL PROJECT AT LEAST 100 CIED PROCEDURES.

(f) THE APPLICANT SHALL HAVE OR OBTAIN WITHIN 12 MONTHS OF BEGINNING OPERATIONS AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS). AN APPLICANT THAT DOES NOT CURRENTLY HOLD THE

CERTIFICATION SHALL ATTEST THAT THE CERTIFICATION WILL BE OBTAINED WITHIN 12 MONTHS OF BEGINNING OPERATIONS.

4. Section 6(1)(d): Added language.

(d) A MINIMUM OF 540 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PCI PROCEDURES.

5. Section 10(2): Added criteria to the project delivery requirements for physicians credentialed by an FSOF to perform PCI.

(g) EACH PHYSICIAN CREDENTIALLED BY AN FSOF TO PERFORM PCI SHALL MEET THE FOLLOWING CRITERIA:

(i) HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR DURING THE MOST RECENT PRECEDING 24 MONTHS;

(ii) HAS COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING PROGRAM;

(iii) IS BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY;

(iv) HAS PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY OPERATOR; AND

(v) HAS A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.

(h) EACH PHYSICIAN CREDENTIALLED BY A FSOF TO PERFORM CIED PROCEDURES SHALL MEET THE FOLLOWING CRITERIA:

(i) PERFORMED AT LEAST 75 DEVICE IMPLANTS AS THE PRIMARY OPERATOR IN THE PREVIOUS 24 MONTHS;

(ii) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER;

(iii) IS CARDIOLOGY BOARD CERTIFIED FOR PERMANENT PACEMAKER IMPLANTS;

(iv) IS EP BOARD CERTIFIED FOR ICD IMPLANTS; AND

(v) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(3)(b).

6. Section 10(2): Added criteria to the project delivery requirements for a diagnostic cardiac catheterization and elective PCI program located at an FSOF.

(m) A DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI PROGRAM LOCATED AT AN FSOF SHALL OBTAIN AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) WITHIN 12 MONTHS OF BEGINNING OPERATIONS AND SHALL HAVE AT LEAST ONE INTERVENTIONAL CARDIOLOGIST ON ITS ACTIVE STAFF MEETING THE FOLLOWING CRITERIA:

(i) HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR DURING THE MOST RECENT 24-MONTH PERIOD;

(ii) HAS COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING PROGRAM;

(iii) IS BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY;

(iv) HAS PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY OPERATOR; AND

(v) HAS A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.

(n) AN FSOF PERFORMING CIED PROCEDURES SHALL HAVE AT LEAST ONE ELECTROPHYSIOLOGIST ON ITS ACTIVE STAFF MEETING THE FOLLOWING CRITERIA:

(i) IS CARDIOLOGY BOARD CERTIFIED FOR PPM IMPLANTS;

(ii) IS EP BOARD CERTIFIED FOR ICD IMPLANTS;

(iii) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(3)(B);

(iv) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER; AND

(v) HAS IMPLANTED AT LEAST 75 DEVICES AS THE PRIMARY OPERATOR IN THE PREVIOUS 2 YEARS POST FELLOWSHIP TRAINING.

7. Section 10(4)(a): Adjusted the maintenance volume requirements for hospitals in rural/micropolitan counties and added maintenance volume requirements for FSOFs. Volume requirements are in line with national guidelines to ensure quality outcomes.

(i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures FOR A HOSPITAL IN A METROPOLITAN COUNTY.

(ii) 150 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES FOR A HOSPITAL IN A RURAL OR MICROPOLITAN COUNTY.

(v) 250 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

(vi) 750 procedure equivalents for a hospital in a metropolitan county OR AN FSOF with one laboratory.

(ix) 200 adult PCI procedures for an elective PCI service without on-site OHS service LOCATED IN A HOSPITAL OR FSOF.

(x) 100 CIED PROCEDURES FOR AN FSOF PROVIDING CIED SERVICES.

8. Section 10(5)(g): Added project delivery requirements for diagnostic cardiac catheterization and elective PCI services at an FSOF.

(g) FOR DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI SERVICES AT AN FSOF, CATHETERIZATION LAB FACILITY REQUIREMENTS SHALL CONFORM TO THE POSITION STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9). THE APPLICANT FACILITY SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THE PRINCIPLES DOCUMENTED IN THIS POSITION STATEMENT.

9. Section 10(6): Added project delivery requirements for FSOFs providing CIED procedures.

(6) COMPLIANCE WITH ALL OF THE FOLLOWING REQUIREMENTS FOR FSOFS PROVIDING CIED PROCEDURES:

(a) MAINTAIN A WRITTEN TRANSFER AGREEMENT AND PROTOCOLS WITH THE TERTIARY CARE CENTER IDENTIFIED IN SECTION 4(3)(b).

(b) MAINTAIN CARDIAC CATH LAB CAPABILITIES INCLUDING PERICARDIOCENTESIS EQUIPMENT ON SITE.

(c) REPORT ACUTE OUTCOMES OF PROCEDURES TO A REGISTRY IDENTIFIED BY THE DEPARTMENT.

(d) MAINTAIN DEVICE FOLLOW UP PROTOCOLS.

10. Section 12: Revised the documentation of projections similar to the surgical services physician commitment process. Volume must come from existing cardiac catheterization services and there can only be commitment of excess volumes whether it's the applicant's existing service or other existing services. Excess is defined as volume in excess of 1200 PE/lab and 300 PCIs per service.

11. Other technical edits.

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Oral comments may be presented during the hearing on Tuesday, April 27, 2021, or submitted in writing by sending an email to the following email address: MDHHS-ConWebTeam@michigan.gov

Please submit written comments no later than 5:00 p.m., Tuesday, May 4, 2021.

If you have any questions or concerns, please contact Tania Rodriguez at rodriguez1@michigan.gov.